CLAIMS

We claim:

1. An extended release multiparticulate composition, comprising:
a plurality of particulates, each comprising:
a core comprising a hydrophilic theraputic agent and a core binder,
a release rate controlling polymer coating covering the core and
a binder-dispersing agent over-coating the polymer coating.

2. The extended release composition of claim 1, wherein the plurality of particulates have an average particle size of about 250 μm to about 1.2 mm.

3. The extended release composition of claim 1, wherein the hydrophilic therapeutic agent is selected from the group consisting of: reboxetine, clindamycin, (-)-S-3-(3-methylsulfonylphenyl)-N-n-propylpiperidine, sumanirole, pramipexole, atenolol, propoxyphene, metformin, metoprolol, amitriptyline, ranitidine, fexofenadine, quinapril, sildenafil, tramadol, verapamil, gabapentin, potassium chloride, alendronate, bupropion, levofloxacin, doxycycline, venlafaxine, allopurinol, isosorbide mononitrate, fosonipril, propanolol, promethazine, captopril, fluvastatin, cimetidine, sumatriptan, nortriptyline, naproxen, calacyclovir, doxepin, amoxicillin, azithromycin, diltiazem, cefprozil, acyclovir, ciprofloxacin, losartan, and pharmaceutically acceptable salts of any of said active agent

4. The extended release composition of claim 1, wherein the hydrophilic therapeutic agent is a salt of clindamycin.

5. The extended release composition of claim 4, wherein the salt of clindamycin is selected from the group consisting of clindamycin hydrochloride, clindamycin phosphate, and clindamycin palmitate.

6. The extended release composition of claim 1, wherein the hydrophilic therapeutic agent is a free base of clindamycin.

7. The extended release composition of claim 6, wherein the free base of clindamycin is clindamycin crystalline free base.

8. The extended release composition of claim 1, wherein the clindamycin is about 20% to about 90% by weight of the plurality of particulates.

9. The extended release composition of claim 1, wherein the core binder comprises ethylcellulose.

10. The extended release composition of claim 1, the core further comprising a core lubricant.

11. The extended release composition of claim 10, wherein the lubricant is magnesium stearate.

12. The extended release composition of claim 1, wherein the release rate controlling polymer coating is an extended release polymer coating.

13. The extended release composition of claim 12, wherein the extended release polymer coating is a copolymer of acrylate and methacrylate with quaternary ammonium groups.

14. The extended release composition of claim 13, wherein the copolymer of acrylate and methacrylate is Eudragit® RS30D or an equivalent thereof.

15. The extended release composition of claim 1, wherein the binder-dispersing agent over-coating the polymer coating is povidone or a derivative thereof.

16. The extended release composition of claim 15 wherein the povidone or a derivative thereof is in a form selected from the group consisting of povidone and cross-povidone.

17. The extended release composition of claim 1, further comprising extra-multiparticulate material compressably commingled with the plurality of particulates.

18. The extended release composition of claim 17, the extra-multiparticulate material comprising an extra-multiparticulate binder.

19. The extended release composition of claim 18, wherein the extra-multiparticulate binder is a cellulose derivative.

20. The extended release composition of claim 19, wherein the cellulose derivative is selected from the group consisting of ethylcellulose, hydroxypropylmethylcellulose, and microcrystalline cellulose.

21. The extended release composition of claim 17, the extra-multiparticulate material comprising an extra-multiparticulate lubricant.

22. The extended release composition of claim 21, wherein the extra-multiparticulate lubricant is magneseium stearate.

23. The extended release composition of claim 17, the extra-multiparticulate material comprising a disintegrant.

24. The extended release composition of claim 23, wherein the disintegrant is a superdisintegrant.

25. The extended release composition of claim 24, wherein the superdisintegrant is croscarmellose sodium.

26. The extended release composition of claim 17, the extra-multiparticulate material further comprising a surfactant.

27. A compressed tablet, comprising:

a plurality of particulates, each comprising:

a core comprising a hydrophilic therapeutic agent and a core binder,

a release rate controlling polymer coating covering the core, and

a binder-dispersing agent overcoating the release rate controlling polymer coating; and

extra-multiparticulate material compressibly commingled with the plurality of particulates, the extra-multiparticulate material comprising a superdisintegrant.

28. The compressed tablet of claim 27, wherein the plurality of particulates have an average particle size of about 250 μm to about 1.2 mm.

29. The compressed tablet of claim 27, wherein the hydrophilic therapeutic agent is selected from the group consisting of: reboxetine, clindamycin, (-)-S-3-(3-methylsulfonylphenyl)-N-n-propylpiperidine, sumanirole, pramipexole, atenolol, propoxyphene, metformin, metoprolol, amitriptyline, ranitidine, fexofenadine, quinapril, sildenafil, tramadol, verapamil, gabapentin, potassium chloride, alendronate, bupropion, levofloxacin, doxycycline, venlafaxine, allopurinol, isosorbide mononitrate, fosonipril, propanolol, promethazine, captopril, fluvastatin, cimetidine, sumatriptan, nortriptyline, naproxen, calacyclovir, doxepin, amoxicillin, azithromycin, diltiazem, cefprozil, acyclovir, ciprofloxacin, losartan, and pharmaceutically acceptable salts of any of said active agent

30. The compressed tablet of claim 27, wherein the hydrophilic therapeutic agent is a salt of clindamycin.

31. The compressed tablet of claim 30, wherein the salt of clindamycin is selected from the group consisting of clindamycin hydrochloride, clindamycin phosphate, and clindamycin palmitate.

32. The compressed tablet of claim 27, wherein the hydrophilic therapeutic agent is a free base of clindamycin.

33. The compressed tablet of claim 32, wherein the free base of clindamycin is clindamycin crystalline free base.

34. The compressed tablet of claim 27, wherein the clindamycin is about 20% to about 90% by weight of the plurality of particulates.

35. The compressed tablet of claim 27, wherein the core binder comprises ethylcellulose.

36. The compressed tablet of claim 27, the core further comprising a core lubricant.

37. The compressed tablet of claim 36, wherein the core lubricant is magnesium stearate.

38. The compressed tablet of claim 27, wherein the release rate controlling polymer coating is an extended release polymer coating.

39. The compressed tablet of claim 38, wherein the extended release polymer coating is a copolymer of acrylate and methacrylate with quaternary ammonium groups.

40. The compressed tablet of claim 39, wherein the copolymer of acrylate and methacrylate is Eudragit® RS30D or an equivalent thereof.

41. The compressed tablet of claim 27, wherein the binder-dispersing agent over-coating the polymer coating is povidone or a derivative thereof.

42. The compressed tablet of claim 41 wherein the povidone or a derivative thereof is in a form selected from the group consisting of povidone and cross-povidone.

43. The compressed tablet of claim 27, the extra-multiparticulate material further comprising an extra-multiparticulate binder.

44. The compressed tablet of claim 43, wherein the extra-multiparticulate binder is a cellulose derivative.

45. The compressed tablet of claim 44, wherein the cellulose derivative is selected from the group consisting of ethylcellulose, hydroxypropylmethylcellulose, and microcrystalline cellulose.

46. The compressed tablet of claim 27, the extra-multiparticulate material further comprising an extra-multiparticulate lubricant.

47. The compressed tablet of claim 46, wherein the extra-multiparticulate lubricant is

magneseium stearate.

48. The compressed tablet of claim 27, the extra-multiparticulate material further comprising a surfactant.

49. A method of treating or preventing a gram-positive bacterial infection in a subject according to steps comprising:

orally administering to the subject an extended release multiparticulate tablet, comprising:

a plurality of particulates, each comprising:

a core comprising clindamycin and a core binder,

a release rate controlling polymer coating covering the core, and

a binder-dispersing agent overcoating the release rate controlling polymer coating; and

extra-multiparticulate material compressably commingled with the plurality of particulates, the extra-multiparticulate comprising a superdisintegrant.

50. The method of claim 49, wherein the hydrophilic therapeutic agent is a salt of clindamycin.

51. The method of claim 50, wherein the salt of clindamycin is selected from the group consisting of clindamycin hydrochloride, clindamycin phosphate, and clindamycin palmitate.

52. The method of claim 49, wherein the hydrophilic therapeutic agent a free base of clindamycin.

53. The method of claim 52, wherein the free base if clindamycin is clindamycin crystalline free base.

54. The method of claim 49, wherein the superdisintegrant is croscarmellose sodium.

55. The method of claim 49, wherein the subject is a mammal.

56. The method of claim 49, wherein the mammal is a human being.

57. The method of claim 49, wherein the gram-positive bacteria infection treated or prevented by the method of treatment is due to a bacteria species of a genus selected from the group consisting of: *streptococci*, *pneumococci*, and *staphylococci*.